

Remarks**Status of the Claims**

Claims 1-43 are pending in this application. Pending claims 18-31, drawn to methods of identifying a modulator of a Lepidoptera calcium channel protein activity, stand rejected. Claims 1-17 and 32-43 were previously withdrawn from prosecution under a restriction requirement. No claim is allowed. No art has been cited against the claimed invention.

Amendments to the claims are made for clarity and to correct punctuation. No new matter is introduced.

1. Patentability Under 35 U.S.C. §101

Elected claims 18-31 stand rejected for a lack of utility under 35 U.S.C. §101. In the instant application, claims 18-31 are drawn to methods for identifying modulators of a lepidoptera calcium channel protein activity. The method claims meet the utility standard required by the statute.

The Examiner declares that the rejection is made because the claimed invention is not supported by either a substantial and specific utility or a well-established utility. However, the pending Office Action text (pages 2-4) is not relevant to the pending elected method claims. The claimed subject matter is not a compound and not a method of using a calcium channel polypeptide. Nor are the claims under prosecution drawn to methods to treat or address the conditions disclosed in the specification.

Instead, the pending claimed subject matter is a research tool. The claims are drawn to methods to identify compounds that are candidates for use in a treatment or application. The Examiner incorrectly states “[t]he claims are directed to calcium channel.” The Examiner further addresses “[t]he claimed polypeptides...”, “...the treatment of the disease...”, “... the nucleic acid sequence claimed.”, “the claimed protein...”, and “[t]he method of using the calcium channel polypeptide...” None of these rejecting comments is relevant to the restricted pending claims. Applicants, having made a proper election in

response to the restriction requirement, expect that prosecution will proceed on the subject matter of the elected method claims.

The claimed subject satisfies the statutory requirements for utility of 35 USC §101. Methods to identify useful compounds are the bedrock tools used by the agricultural chemical, pharmaceutical, and veterinary industries in their quests to address real-world conditions and diseases. If methods for identifying compounds that would alter the activity of a protein are not useful, what is the purpose of companies in these industries spending millions of dollars to develop and use such assay methods?

The Examiner does not cite the USPTO Guidelines for Examination of Applications for Compliance with the Utility Requirement (MPEP 2107; hereinafter "Utility Guidelines"). However, the pending Office Action quotes irrelevant phrases directly from this analysis for utility as indicated on page 8 of this Response and Amendment. Relevant to the claimed subject matter, the Guidelines directly support the utility of a novel method to identify a compound having an activity of interest (MPEP section 2107.01, C, III) as follows:

'Courts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an "immediate benefit to the public" and thus satisfies the utility requirement. As the Court of Customs and Patent Appeals held in *Nelson v. Bowler*:

'Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility.'

Nelson v. Bowler, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).'

'...Similarly, courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical

product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition.'

'... Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995).'

'Accordingly, Office personnel should not construe **35 U.S.C. 101**, under the logic of "practical" utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans.' (citations deleted)

Thus, research tools are patentable if their use is directed to the discovery of the properties of other materials, not to the discovery of their own properties. The majority opinion in *In re Fisher*, 421 F3d 1365 (Fed. Cir. 2005) makes this abundantly clear. The claims in that case were drawn to Express Sequence Tags (EST's) obtained from cDNA libraries of maize. The nature of the proteins encoded by the genes represented by the EST's was unknown, as was their function. The *Fisher* majority distinguished the utility of such compositions from the utility of research tools using the example of a microscope as follows:

'A microscope has the specific benefit of optically magnifying an object to immediately reveal its structure. One of the claimed EST's, by contrast, can only be used to detect the presence of genetic material having the same structure as the EST itself. It is unable to provide any information about the overall structure, let alone the function of the underlying gene. Accordingly, while a microscope can offer an immediate real-world benefit in a variety of applications, the same can not be said for the claimed EST's.'

The CAFC found this utility sufficient under the statute to support patentability of the claimed subject matter. In like manner, Applicants' invention does not simply further define or characterize the research method or the lepidoptera calcium channel protein.

Rather, the method assesses the characteristics of compounds other than the lepidoptera calcium channel protein to identify modulators of that protein activity. As does the microscope invoked by the CAFC, the claimed method reveals something about something other than itself, and what is revealed about that “other something” is itself immediately useful.

The Examiner cites *Brenner v. Mason*, 383 US 519 (1966) to support the rejection of claims 18-31 for lack of utility:

‘Congress intended that no patents be granted on a[n] chemical compound whose sole “utility” consists of its potential roles as an object of use-testing...a patent is not a hunting license. It is a not a reward for the search, but compensation for its successful conclusion.’

The Court in *Brenner* did reach a holding of non-patentability of a compound whose function was not known based on the utility requirement. However, it specifically declined to reach beyond the issue before it to make a holding as to the patentability of method claims in *Brenner*.

In contrast to the facts in *Brenner*, Applicants’ claims are drawn to methods to identify a modulator of a specific protein. The modulator identified with the method can be used to address conditions disclosed in the specification and shown in the working examples. The claims at issue are not drawn to a chemical compound, composition, or process to prepare a compound whose function is not known. Furthermore, a function of the compounds identified by the claimed method is known. The holding in *Brenner* is not applicable to the present claims.

The Utility Guidelines advise that a rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record. Applicants’ invention is useful in the manner described in MPEP 2707.01, not

only in the pharmaceutical industry, but also in the agrochemical and veterinary industries. The stated utility is not a “throw away utility”, but is credible, substantial, and specific under the Guidelines and the Statute. The claims are particularly drawn to methods for identifying a modulator of a *Lepidoptera* calcium channel protein activity useful for controlling harmful organisms and in preventing infestation or damage caused by harmful organisms (see paragraph 1087). Support for Applicants’ position is found in the specification at paragraphs 1056-1087, and in the Figures, particularly Figs 3-5.

In light of the above discussion, Applicants respectfully request the withdrawal of the rejection for lack of utility and reconsideration of the claims under consideration.

3. Patentability Under, 35 U.S.C. §112, first paragraph:

A. In light of Applicants’ rebuttal of the rejection for lack of utility under 35 U.S.C. §101 and the procedure set out under the Utility Guidelines, the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

The rejections under 35 USC §101 and under §112, first paragraph, are both based on the same rationale—a putative lack of utility with regard to how to use the claimed method of identifying a modulator of a lepidoptera calcium channel protein activity.

The Office Action continues in its rejection by complaining that “the specification does not provide a nexus between the method of modulation of calcium channel and preventing infestation or damage by harmful organism.”

Applicants disagree that no nexus is provided between the method of identifying compounds that modulate calcium channel protein activity and prevention of infestation or damage by harmful organisms. The nucleic acids used in the claimed method encode calcium ion channels useful in screening assays to identify candidate modulating compounds. Modulating the expression of the protein by contact with a test compound (as measured by generating a signal that represents the interaction of an amino acid

sequence with the tested compound) suggests that the test compound disrupts the physiology of the insect in a way that may be exploited upon further optimization for ultimate use. The specification supplies such nexus at pages 1 [0002-0003] and 8 [0107-0110]. Example 6 at page 20 specifically reports modulation of functional expression of Tobacco Budworm voltage-gated calcium channel protein activity. There is no reason to doubt Applicants' straightforward statements.

No requirement exists under the statute that compounds identified by use of the claimed method must prove commercially useful in controlling or preventing infestation or damage by an insect. In the set of candidate compounds identified by the method, only a subset may have sufficient activity to receive approval for use or even to justify testing in the long process required for such approval. But this does not undermine the usefulness of the method to identify such compounds.

As recently explained in the precedential opinion of *Ex parte Kubin* (PTO Bd. App., May 31, 2007), a rejection for lack of enablement on the basis of undue experimentation is not appropriate where the amount of experimentation to practice the full scope of the claimed invention would have been routine, even if extensive. Since the methods used to practice the full scope of Applicants' claimed invention were routine, even if extensive, as of the 8 November 2002 priority date, the pending rejection for lack of enablement should be withdrawn. Experimentation to practice the claimed methods is not undue.

Finally, the statutory requirements must be applied consistently in comparable cases. Applicants understand that each invention must be examined on its own merits, but fundamental fairness requires that the criteria for patentability be applied uniformly by the Office to maintain a standard expectation of what is and what is not acceptable to show utility. Therefore, Applicants expect the same criteria to be applied to examination of the instant claims as were used in granting US 7297504, US 6207410, and US 5401629. These three patents all provide screens for identifying compounds. None were denied for lack of utility.

Having satisfactorily rebutted the *prima facie* rejection based on lack of utility under 35 U.S.C. 101 and 112, first paragraph, Applicants respectfully request the withdrawal of the rejections, reconsideration of claims 18-31 as amended, and their prompt allowance.

Conclusion

In view of the foregoing, Applicants respectfully assert that the independent claim 18, as amended, patentably defines the present invention. Further, the dependent claims should also be allowable for the same reasons as their respective base claims and further due to the additional features that they recite. Therefore, Applicants request reconsideration, withdrawal of the rejections, and early allowance of the presented claims. Separate and individual consideration of the dependent claims is respectfully requested.

Respectfully submitted,

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